

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

First Named
Inventor :

Christopher Lee Berg et al.

Appln. No.: 10/623,179

Filed : July 18, 2003

For : METHOD AND APPARATUS FOR
REPLACING KNEE-JOINT

Docket No.: M81.12-0060

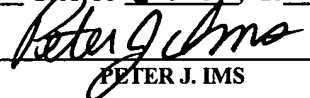
Group Art Unit: 3732

Examiner: A. Ramana

PRE-APPEAL REQUEST FOR REVIEW

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PETER J. IMS

Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal.

Claim 19 stands as rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,373, 709 (Whitt). In the March 1, 2006 Office Action, the Examiner alleged that the Whitt patent discloses a surgical limb holder 10 that can be used to hold a limb in any position, the holder mounted to a surgical table having a support 11, arms 29 and a flexible strap 42 that can be used to restrain a lower portion of a leg or "lower leg" (Figs. 1 and 3, col. 1, lines 19-21 and col. 2, lines 18-39).

Applicants respectfully disagree that the Whitt patent anticipates claim 19. Claim 19 defines the retractor support as being mounted to the surgical table and having first and second arms that are extendable along opposite sides of the knee. There is no disclosure in the Whitt patent of the defined structure. Rather, the Whitt patent discloses an upwardly extending generally U-shaped support that engages the circumference of the thigh. The support disclosed in the Whitt patent is not extendable along opposite sides of the knee as claimed.

Claim 19 also defines the present invention as having a flexible strap extending between the distal end portions of the support arms for engaging the lower leg to provide a generally downward force against the lower leg to retain the lower leg in position. The strap disclosed in the Whitt patent is not utilized to provide a downward force to the thigh. Rather the strap may be utilized to further restrain a limb. See Col. 3, lines 23-25. The strap in the Whitt patent does not provide a downward force to retain the lower leg in position as claimed.

The Examiner relies upon *In re Schreiber* to maintain the anticipation rejection of claim 19 by stating that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). However, the anticipation rejection was affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner).

A U-shaped support 13 attached to a substantially vertical stanchion member 11, irrespective of the rotational movement about its axis and height, would be positioned substantially vertically around opposite sides of the knee. To then attach the strap 40 to the ends of the support members 13 would obstruct access to the knee joint and prevent or hinder the surgical procedure. Therefore, the device disclosed in the Whitt patent is not capable of being positioned on opposite sides of the knee and also retain the lower leg as claimed for a knee joint surgery.

Also, the Examiner relies upon the statement that the device disclosed in the Whitt patent is adjustable such that the limb can be held in any position which will enhance or facilitate surgery (Col. 1, lines 19-22). However, the Whitt patent discloses that the stanchion member 11 slides and rotates within the vice 14 to adjust the height and attitude of the support. (Col. 2, lines 18-21 and lines 27-31). The position of the device relative to the patient is adjusted by moving the vice 14 along the sides or ends of the operating table on a track 38. (Col. 2, lines 23-26). Movement along the track 38 of an operating table and vertical and rotational movement of the stanchion within the vice, does not provide movement to of the device into any position that will enhance surgery as the device is only useful when the limb to be operated upon is near the edge of the operating table.

Contrary to the allegations in the Office Action, the structure disclosed in the Whitt patent is not capable of being positioned along opposite sides of the knee and having a flexible strap therebetween for engaging the lower leg as claimed while being able to perform a knee surgery. Therefore, the Whitt patent does not anticipate claim 19.

Claims 17 and 18 stand as rejected under 35 U.S.C. § 103(a) as being obvious over the Whitt patent. The Office Action incorporated the allegations with respect to the anticipation rejection of claim 19 and stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the limb holder 10 to restrain the lower leg or “tibia” to provide support without discomfort.

Applicants respectfully disagree that claims 17 and 18 are obvious as the Whitt patent does not disclose all of the claim elements. Applicant incorporates the arguments made with respect to claim 19. Further, the strap defined in claim 17 is utilized to engage the lower leg with a downward force to retain the lower leg in a selected position during surgery. In contrast the strap disclosed in the Whitt patent does not provide a downward force. Rather, the strap disclosed in the Whitt patent is (1) not absolutely necessary to practice the invention (Col. 2, lines 65- 67), and (2) is utilized as a further restrainer for the limb (Col. 3, lines 22-25).

There is no disclosure in the Whitt patent of the strap being utilized to provide a downward force upon the lower leg as claimed. Rather the limb is retained in a position with an upward force on an underside of the limb with the U-shaped member. Utilizing a support under a leg to retain the leg in a selected position does not disclose the claim element of utilizing a strap to engage an upper side of the lower leg to provide a downward force to retain the lower leg in a selected position.

Also, the disclosure of the Whitt patent does not disclose positioning the knee in an elevated position such that the knee is facing generally upwardly as claimed. Rather, the Whitt patent discloses the important advantage of holding the limb over the edge (dangling over) the operating table which allows the knee to be flexed and fully bent as necessary during the procedure. (Col. 3, lines 17-22). Having a portion of a limb dangling over the edge of a table does not position the knee joint in a position facing generally upwardly as claimed.

Also, the Office Action impermissibly rejected claims 17 and 18 because the claimed invention was used as a road map to allege obviousness. The Whitt patent discloses the important advantage that the limb (lower leg) dangles over the edge of the table. However, the Office Action ignores this teaching to allege that the lower leg is retained in a selected position by applying a downward force on the lower leg.

The Office Action rejected claims 9-16 as being obvious by the combination of Fowler Jr. U.S. Patent No. 6,190,312 (hereinafter the '312 patent) in view of Fowler U.S. Patent No. 5,964,698 (hereinafter the '698 patent) and Greishaber U.S. Patent No. 4,813,401 (hereinafter the '401 patent). Among other allegations, the Office Action alleges that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to mount the retractor apparatus of the combined '312 patent and the '698 patent to an operating table, as taught by the '401 patent, as it is common knowledge in the retracting art to support a conventional retractor frame by mounting it to a surgical table.

Applicants respectfully disagree that claims 9 -16 are made obvious by the '312 patent in view of the '698 patent and the '401 patent because, at least, there is no teaching or suggestion to combine the '312 patent with the '401 patent. In *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999), the Federal Circuit emphasized that, to reject an inventor's claim for obviousness in view of a combination of prior art references, a showing of a suggestion, teaching or motivation must be "clear and particular". The mere fact that prior art can be modified does **not** make the modification obvious unless the prior art taught or suggested the desirability of the modification. *In re Gordon*, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

The '312 patent discloses a variable geometry retractor frame that is conformed to fit a surface of the patient's body at a surgical site. (Col. 4, lines 59-63 and Col. 8, lines 13-14). The variable geometry frame allows for improved placement of the clips on the frame where the clips engage an elastic member that is utilized to retract flesh. (Col. 3, lines 37-41). The retractor frame supported by a patient provides adequate support for the elastic member that is utilized to retract flesh.

The '401 patent discloses a table mounted retractor support that supports retractors having hinged, rigid handles that do not hinder the surgeon's movement during the operation.

(Col. 2, lines 31-35). The '401 patent also discloses a retractor holder that is easily movable to a new position on the retractor frame without having to disturb the position of the other retractor structures. (Col. 2, lines 42-45).

There is no clear and particular motivation, teaching or suggestion that would lead one of ordinary skill in the art to combine a reference that discloses a variable geometry retractor frame that is supported by the patient's body to provide better placement of retractors with a reference that discloses retractors with rigid, hinged handles and an improved clamp for a table mounted support to provide better access to a surgical site to allege that the claimed invention is obvious.

In re Clay, 966 F.2d 656, 659-60 (Fed. Cir. 1992) (A reference that discloses the same purpose as the claimed invention relates to the same problem and that fact supports use of the reference in an obviousness rejection.) Neither reference addresses the purpose of the claimed invention where the tibia is moveable during a knee-joint replacement surgery without re-engaging the retractors with the flesh or reattaching the retractors to the support.

As is clear from the above discussion, the Office Action used the claimed invention as a road map to allege claims 9-16 are obvious, as there is no teaching, suggestion or motivation to make the combination of references. In view of this, it is believed that the obviousness rejection cannot be maintained and it is requested that the rejection be withdrawn and the claim allowed.

Finally, the Office Action alleges that the Replacement Drawing of Figure 2 and Exhibits A-C were not submitted with the Amendment After Final. While Replacement Drawing of Figure 2 and Exhibits A-C were inadvertently omitted from the Amendment After Final, they were submitted in the September 20, 2005 Amendment, and Applicants hereby submit a copy of a postcard proving prior receipt.

Respectfully submitted,

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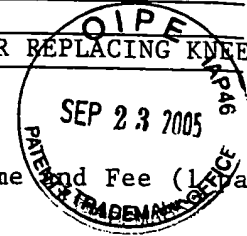
Receipt is hereby acknowledged by the Assistant Commissioner of Patents and Trademarks of the following items in the matter of:

Applicant : Christopher L. Berg et al.

Serial No./Patent No.: 10/623,179

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Title/Mark : METHOD AND APPARATUS FOR REPLACING KNEE JOINT



1. Credit Card Payment Form (1 page)
2. Fee Transmittal (1 page)
3. Petition for One-Month Extension of Time and Fee (1 page)
4. Amendment (8 pages)
5. Replacement Drawing (1 page; Fig. 2)
6. Exhibits A, B, C
7. Information Disclosure Statement including Form PTO-1449 (3 pages) and cited references (27)

Atty/Sec ZPS:cnn Date: 9-21-05 File No. M81.12-0060